



September 27-28, 2017

COMMENTS FOR EPA'S SAB CAAC MEETING

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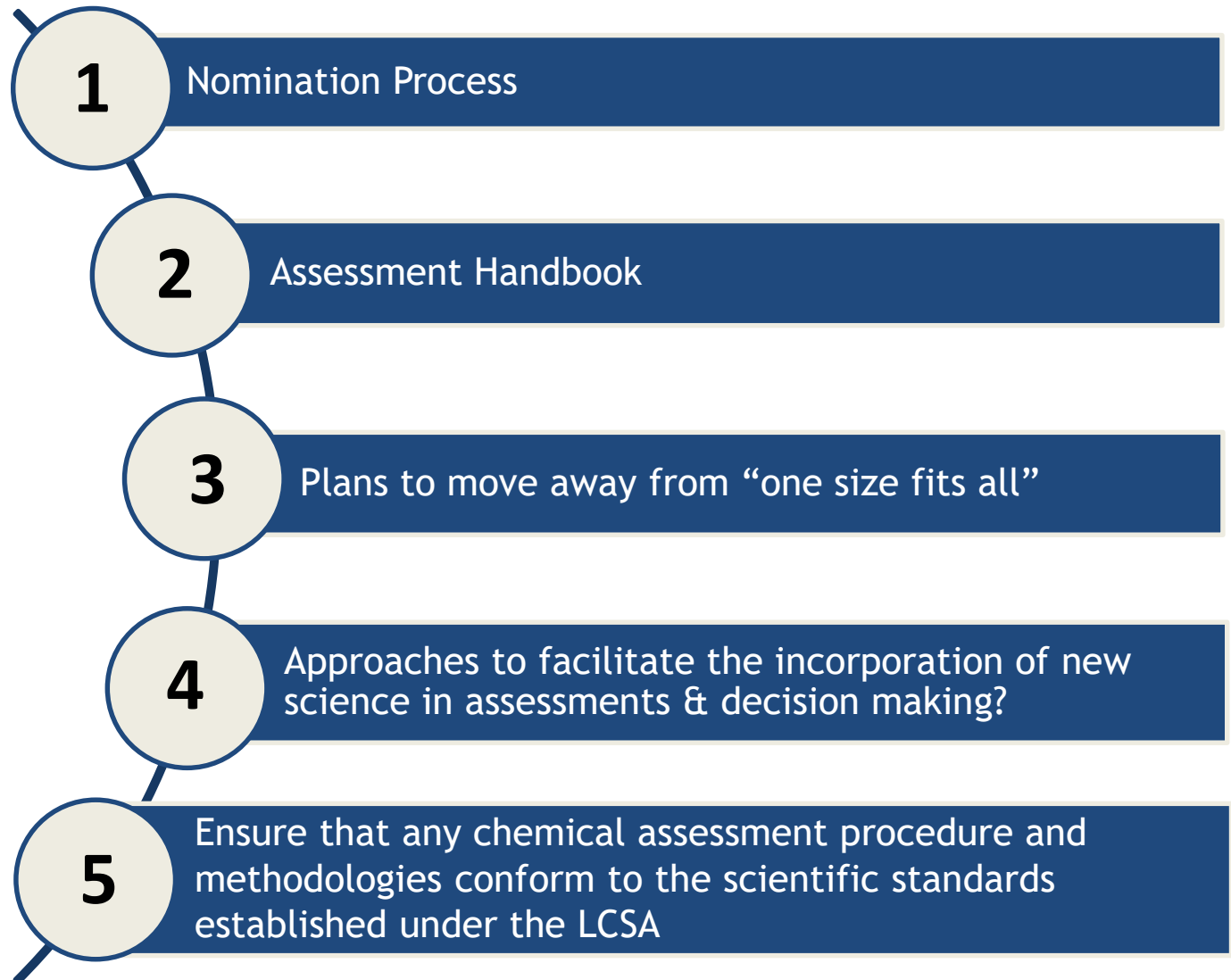




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Improvements and Clarification Needed



Chemical Prioritization and Nomination

Table 1. Status of chemicals currently being assessed by the IRIS Program (December 2015).

Step in IRIS Process	Assessments
6: Final Agency Review/Interagency Science Discussion	
5: Revise assessment	Ammonia (inhalation) Ethylene oxide (inhalation, cancer) Trimethylbenzenes
4: Public comment; Peer review	Benzo[a]pyrene
Pre-4: Assessments released prior to the NRC (2011). They are being revised to incorporate elements of systematic review and will be re-released to step 4.	Acrylonitrile n-Butyl alcohol Formaldehyde Polycyclic aromatic hydrocarbon (PAH) relative potency factors
3: Interagency Science Consultation	t-Butyl alcohol Ethyl t-butyl ether (ETBE) Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)
2: Agency Review	
1: Draft development	Arsenic, inorganic Butyl benzyl phthalate Chromium VI Dibutyl phthalate Diethyl phthalate Di-isobutyl phthalate Di-isononyl phthalate Ethylbenzene Hexabromocyclododecane Naphthalene Polychlorinated biphenyls (PCBs; noncancer)
Problem formulation	

Table 2. Groups of chemical assessments in priority order.

Group	Chemicals
1	Manganese Mercury Methylmercury Nitrate and nitrite Perfluoroalkyl compounds Vanadium and compounds
2	Acetaldehyde Ammonia (oral) Cadmium and compounds Uranium (effects not associated with radioactivity)
3	Di-(2-ethylhexyl) phthalate Dichlorobenzene isomers Methyl t-butyl ether (MTBE) Nickel and compounds Styrene

Clarification Needed

- ☐ What is the process for prioritization of chemicals?
- ☐ How do the draft assessment plans fit into this process?
- ☐ Chloroform in 2015 Multi-year agenda ?
- ☐ Are there plans to revise the IRIS agenda?

Recommendations for Improvement

- ☐ Prioritizes should be based on clear regulatory need
- ☐ Opportunity for public comment on priorities should allowed
- ☐ Agenda should be updated regularly to illustrate when priorities change

Assessment Handbook

Clarification Needed

- ☐ When will the draft handbook be released?
- ☐ Will the draft handbook be available for the CAAC to review?
- ☐ Will the draft handbook be available for public comments?

Recommendations for Improvement

- ☐ Draft handbook should be released for public comment
- ☐ Draft handbook should undergo review by the CAAC
- ☐ Final handbook should incorporate comments from the public and CAAC
- ☐ No assessments should be released unless they clearly demonstrate how they conform with the final handbook

Move away from “one-size-fits-all”

Clarification Needed

- ☐ How will EPA decide if screening level assessment versus a more involved assessment is needed?
- ☐ Are the data needs different depending on the type of assessment conducted?
- ☐ Is there criteria for this approach?

Recommendations for Improvement

- ☐ Clearly define the different types of assessment the program will conduct
- ☐ Clearly define the data required for each assessment type

Approaches to Incorporate New Science

Clarification Needed

- ❑ When will EPA release a draft protocol? Will it include the process that EPA will use to:
 - Evaluate study quality for each stream of evidence?
 - Use the study quality information to integrate data to reach conclusions?
- ❑ Will the agency release a weight of evidence framework for assessments?
- ❑ How will EPA keep up-to-date on current publications for use in its assessments and how will this information be shared with the public?

Recommendations for Improvement

- ❑ Identify what considerations are needed to determine a study to be of high, medium or low quality.
- ❑ Identify study quality characteristics and describe how each of the studies meets, or does not meet, these criteria (e.g. for animal data, such criteria could include a clear evaluation of study design, sample size, statistical power, and the dose response and exposure characterization)
- ❑ Discuss how the quality evaluation influenced a study's use in the weight of evidence evaluation